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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,750	02/19/2004	Joseph P. Vacanti	MIT 6917 (CMCC 450) DIV	5014
23579	7590	12/13/2005	EXAMINER	
PATREA L. PABST PABST PATENT GROUP LLP 400 COLONY SQUARE SUITE 1200 ATLANTA, GA 30361			ISABELLA, DAVID J	
			ART UNIT	PAPER NUMBER
			3738	
DATE MAILED: 12/13/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

### Period for Reply

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1) ☒ Responsive to communication(s) filed on 03 October 2005.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

4) ☒ Claim(s) 1-5 and 8-17 is/are pending in the application.  
4a) Of the above claim(s) 16 and 17 is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 1-5,8-15 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All    b) ☐ Some \*    c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

1) ☒ Notice of References Cited (PTO-892)  
 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_.

- Part of Paper No./Mail Date 20051210

***Status of the Claims***

Claims 1-5,8-17 are currently pending for action. Claims 6 and 7 have been cancelled. Claims 16 and 17 have been newly added. Claims 1,2,15 have been amended.

***Election/Restrictions***

Newly submitted claims 16 and 17 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims are directed to a cell matrix construct seeded with myofibroblasts. The original claims were directed to a method for making a cell matrix construct including implanting the construct into an animal. The construct of claims 16-17 does not require the specific in vivo harvesting of the construct and therefor is directed to subject matter not originally considered.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 16 and 17 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5,8-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sparks (3514791) in view of Schmidt, et al (4520821), Mikos (5514378) or Griffith-Cima et al (5709854) and further in view of either of Jauregui (4795459) or Tang et al (4916193).

Sparks discloses a method for making a cell-matrix construct for use as a heart valve comprising implanting into an animal a fibrous matrix formed of a polymer that has been seeded with specific selected cells. Sparks fails to teach that the matrix is biodegradable. Schmidt, et al, Mikos and Griffith-Cima et al teach the use of biodegradable matrix which is designed to allow biological tissue ingrowth to form a structure before the matrix is completely bioabsorbed. To replace the non-absorbable mesh of Sparks with an absorbable matrix as taught by Schmidt, et al, Mikos or Griffith-Cima et al to allow for a degradable template for new tissue formation would have been obvious to one with ordinary skill in the art. Each of Jauregui and Tang et al teaches the equivalent between resorbable material and non resorbable materials used in heart valve applications similar to that as disclosed in column 4 of applicants specification. Applicant specification fails to teach and/or disclose any unobvious benefits or

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criticalities in the selection of the materials used for the seeding of the cells.

Accordingly, examiner maintains that the materials used are well known in the art and are, in many instances, known equivalents as taught by Jauregui or Tang et al. It should be evident that at the time of Sparks invention (1967) the use of resorbable material in tissue applications was in its infancy. At the time of applicant's invention (2004), great strides have been made in the prosthetic art in replacing non-resorbable materials with resorbable materials for various known benefits. The use of resorbable material as the substrate for seeding cells to form a tissue construct would have been obvious to one with ordinary skill in the art from the teachings of any of the secondary references. With respect to the limitation of "withstand repeated stress and strain", the device of Sparks as modified would inherently possess the properties that would be capable of withstanding cyclic stresses and strains since the valve is designed to function as a replacement of a natural existing valve.

Claim 2, see cells disclosed by Sparks.

Claim 3, Sparks discloses the steps of culturing a matrix at a first site then transplanting the new tissue to a desired site.

Claim 4, one embodiment disclosed by Sparks is a heart valve.

Claim 5, see cells of sparks or Schmidt, et al.

Claim 8, the newly formed heart tissue of Sparks would inherently possess the strength, flexibility and/or pliability of the tissue it is to replace.

Claims 9 and 10, see materials disclosed by Schmidt, et al, Mikos or Griffith-Cima et al.

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Claim 11, see Mikos.

Claims 12-14, see Mikos or Griffith-Cima et al.

Claim 15, see construct of Sparks as modified by either of Schmidt, et al, Mikos or Griffith-Cima et al.

### ***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-THURSDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID J. ISABELLA  
Primary Examiner  
Art Unit 3738

DJI  
12/10/2005